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Chairman Deal, Ranking Member Brown, Members of the Committee:

On behalf of Medtronic and the millions of patients we serve who suffer from chronic diseases such as chronic pain and Pulmonary Hypertension, I thank you for the opportunity to be here today. My name is Jake Vander Zanden and I am the Vice President and General Manager of Medtronic's Global Pain Management Division. Medtronic, headquartered in Minnesota, is the world's leading medical technology company that provides lifelong solutions for people with chronic disease. With deep roots in the treatment of heart disease, Medtronic now provides a wide range of cardiovascular, neurological, gastro-uro, spinal and diabetes therapies that help physicians solve the most challenging, life-limiting medical problems that exist today. In fact, every six seconds, someone's life is saved or improved by a Medtronic technology. I think our mission says it best: "Medtronic is firmly dedicated to alleviating pain, restoring health and extending life throughout the world."

As a company that is investing over $1 billion into research and development this year alone, Medtronic shares the Subcommittee's commitment to increasing our understanding of these conditions and continually improving the therapies available to patients. Today, I would like to share with you information on some of the therapies that Medtronic currently has available in the areas of chronic pain and Pulmonary Hypertension, and provide a glimpse into a few of the innovative treatments we have on the horizon.

Chronic Pain

Chronic pain is an epidemic in this country:

- Approximately 25 percent of the American population suffers from chronic pain – that's one in every four people
- Each year, more than 40 million physician visits are related to pain
- The economic impact is staggering - 515 workdays are lost as a result of pain with an economic cost of nearly $50 billion
- Annually, an astounding $100 billion in medical expenses are incurred due to chronic pain

And these figures don't begin to tell the countless stories of suffering, depression and isolation – even suicide - experienced by chronic pain sufferers and the tremendous impact this has on a pain sufferer's family and loved ones.

Unfortunately, chronic pain is not easy to treat. Dr. Joel Seres may have said it best when he offered, "Chronic pain infers the failure of medical care. If previous treatment had been successful the patient would not be experiencing pain." The reality is that many patients simply give up in their search for relief and instead decide to live their lives suffering from chronic pain. It is exactly these patients that Medtronic serves with our pain therapies.

Building on proven core Medtronic technologies, like the pacemaker, used to treat chronic disease in other areas of the body, Medtronic has successfully treated hundreds of thousands of people who suffer from chronic pain with our neurostimulation and drug delivery therapies. These are clinically proven and minimally invasive options for those who had lost hope that they could find relief and live life to the fullest again. While these therapies are not for everyone, they do provide a viable option for those patients who have not otherwise been successfully treated.

Neurostimulation is a type of implantable pain therapy that stimulates the spinal cord with mild, electrical impulses that block pain signals from reaching the brain, essentially replacing the pain signals with a mild tingling sensation.

The Medtronic neurostimulator is small (about the size of a stopwatch), and is surgically placed under the skin where it sends the impulses to the spinal cord through one or more special "insulated" wires called leads, that are also surgically placed. Based on the needs of individual patients, physicians can customize the pain relief to maximize the effectiveness of the treatment. This device is used to treat individuals suffering from pain as a result of back surgeries, complex regional pain syndrome, as well as degenerative disk disease and painful neuropathies.

There are two types of fully implantable neurostimulators available, rechargeable and non-recharageable, allowing physicians to choose the right device to best address the pain management needs of their patient. The neurostimulation systems typically consist of an implantable neurostimulator, the implantable lead and extension. Additionally, a programmer is used by physicians and patients to adjust the level of stimulation within physician prescribed limits as well as turn the system on or off.

More than 150,000 people worldwide have received Medtronic neurostimulation systems for pain, including the famed comedian, Jerry Lewis, whom some of you have met – perhaps most recently in September when he visited Capitol Hill in support of H.R. 1020, the "National Pain Care Policy Act."

In addition to our neurostimulation system, Medtronic manufactures the world's only implantable, programmable drug infusion systems. Over 100,000 people have been treated with these systems throughout the world. These systems, commonly referred to as "drug pumps," consist of an implantable, programmable pump placed under the skin of the abdomen and a catheter that is placed in the intraspinal space surrounding the spinal column, to deliver liquid morphine directly to where it's needed. The systems, like the

spinal cord stimulators, include a "remote control" or patient programmer. These systems are also pre-programmed by physicians with the appropriate dose of medication. We recently received FDA approval for the first "remote control" that allows patients to administer their own "supplemental" doses of pain medication, when they need it, through our implantable drug pumps.

I'll also point out that because our drug pumps deliver medication directly into the intraspinal space, the dose required to manage the patient's chronic pain is typically only a small fraction of the amount required by oral (ie, pills) or other administration. As a result, the side effects are generally significantly reduced. For example, our pumps may better enable an end-stage cancer patient to spend her final months in the company of family and friends, without the high levels of drowsiness, and other side effects that can arise from high-dosage oral pain medications.

Our spinal cord stimulation devices, as well as our "drug pumps" for chronic pain, often are implanted in patients because other options to manage their pain have failed. Instead, patients continue to have pain after repeated back surgeries, or they may have suffered other injuries or chronic conditions that leave them with persistent, debilitating pain. A significant number of patients use them to manage the severe pain associated with the progression or treatment of malignant cancer, providing them better quality of life.

Future Technologies for the Treatment of Chronic Pain

While our neurostimulation and drug delivery systems have provided relief to hundreds of thousands of those with chronic pain, there are still too many people who are suffering in silence, and who need to know about these additional medical options to adequately manage their pain.

We believe that new technologies are providing better, more cost-effective medical outcomes. For example, our neurostimulator called Restore, which was made available to patients in the U.S. this past spring, builds on our existing neurostimulation system by offering a rechargeable battery, which benefits patients living with the most severe types of pain who might otherwise limit the use of their neurostimulator to conserve or "hoard" the battery power that's available through a lower-power model. With both the neurostimulator and the pumps, the size of the devices have become significantly smaller over the years, and the features have been enhanced to provide both the physician and patient greater control in managing pain

We are also expanding the conditions for which this type of implantable, electricity-delivering therapy can be used. Studies are currently underway to test the feasibility of using neurostimulation to treat severe, chronic migraine patients. We are hopeful that this therapy will provide relief to the more than 28 million Americans who suffer from migraine headaches that cannot be treated with standard migraine treatments.

Future products will no doubt be smaller to improve patient comfort and satisfaction with these devices. New "sensing" technology under development could drive change in the

way patient outcomes are measured, by allowing physicians to measure patient improvement as a result of our devices, more objectively than they can now.

Patients Must have Access to Available Treatments

As I previously mentioned, chronic pain is not easy to treat and I am confident that industry, clinicians and most importantly patients would greatly benefit from research that would give us a better understanding of the causes of pain and lead us to improved treatment options. Medtronic invests in many projects each year to support on-going research efforts in the field of pain.

Unfortunately, many people who are currently living with chronic pain are looking for more immediate solutions for their chronic pain. Many chronic pain sufferers have not found the relief they need due to unnecessary barriers that hinder access to new therapies. While our technologies continue to advance, without patient access to these therapies, the under-treatment of pain will continue to be one of this country's top public health problems.

Medtronic has actively engaged with the patient and provider community to support H.R. 1020, the "National Pain Care Policy Act", introduced by Congressman Mike Rogers. This piece of legislation systematically addresses many of the factors that have lead to the under-treatment of chronic pain. We are grateful to Congressman Rogers for his leadership in raising awareness of this important public health concern.

A disturbing barrier to access is simply a lack of understand of the array of clinically effective therapies already available. Forty percent of people with chronic pain do not go to the doctor for their pain because they believe that nothing can be done to treat it. In a study conducted by the Mayday Fund, 92 percent of respondents considered pain to be a part of life and nearly 35 percent would wait until the pain becomes unbearable before taking medication.

When they do visit a physician, treatment is often inadequate for over half of all patients seeking care, forcing them to change physicians before they find relief. Societal beliefs about pain have reinforced the idea that living with pain is a sign of strength. Addressing these misconceptions by helping to elevate understanding of this disease will greatly assist chronic pain sufferers in getting the help they need.

There are also institutional barriers to effective pain treatment. For many years medical schools addressed the treatment of pain as an afterthought associated with an underlying condition. Increased understanding about the science of pain has helped to define pain as a condition that needs to be treated and taught as a distinct medical condition. Medtronic supports the initiatives contained in the Roger's bill to help ensure that all physicians have access to current information on the wide array of pain therapies available to patients today. With enhanced education, perhaps we will see more internists and general practitioners recognize chronic pain and have knowledge or available referral and treatment options.

While there isn't a simple solution to this complex disease, raising the visibility of the problem of under treatment and starting the national dialogue on how to ensure that chronic pain sufferers get the care they need is a good first step in addressing the problem. Information sharing may be one of the easiest and most cost-effective ways to begin to chip away at the barriers preventing optimal pain treatment. Research to better define the chronic pain patient population, and public awareness campaigns aimed at educating the public on the nature of this disease, would dramatically improve the treatment of pain in this country.

Pulmonary Hypertension

Pulmonary Hypertension (PH) is a rare, debilitating and ultimately fatal disease of the lungs that affects approximately one or two people per million, totaling approximately 100,000 people worldwide. Pulmonary hypertension is a rare blood vessel disorder in which the pressure in the pulmonary artery (the blood vessel that leads from the heart to the lungs) rises above normal levels and may become life threatening. Symptoms of pulmonary hypertension include shortness of breath with minimal exertion, fatigue, chest pain, dizzy spells and fainting.

The cause of Primary Pulmonary Hypertension is a mystery, but is thought to have a latent genetic component that is "activated" after a viral or bacterial infection in the blood vessels that supply the patient's lung tissue. Secondary forms of the disease, which is more frequently observed, are seen as an adverse effect of the now-banned diet pills Redux and fen-phen and as a complication of lupus and other rheumatologic disorders. How and why this combination of drugs caused the increase is not well understood, but this "new" population is primarily young women between the ages of 21 and 40.

Medtronic MiniMed, our diabetes business located in Northridge California, offers a delivery system for the administration of Remodulin, a drug that dilates affected blood vessels in the lung tissue increasing blood flow and improving oxygen exchange. Patients receive this drug through the use of Medtronic's medication delivery pump that delivers the drug under the skin and is similar to an insulin pump used to treat Type I diabetes. Many patients have found the medication pump to be a more convenient way to administer the therapy as the pump is about the size of a pager, it is totally portable, and delivers smaller doses, which is more readily absorbed and with fewer side effects.

Given the devastating nature of this disease and the need for increased research, Medtronic strongly supports H.R. 3005, the "Pulmonary Hypertension Research Act of 2005," which creates three Centers of Excellence at the National Institutes of Health dedicated to learning more about this disease as well as instituting an important public awareness campaign aimed at increasing the patient and medical community's knowledge of this disease.

Conclusion

We are grateful for the Subcommittee's interest in both Pulmonary Hypertension and chronic pain and thank you for the opportunity to discuss some of the therapies Medtronic has made available to suffering patients. While Medtronic shares the vision of finding a cure for pulmonary hypertension and chronic pain, we continue to look for ways to improve the quality of life for those afflicted with these and many other chronic conditions. We welcome the opportunity to work with this Subcommittee to increase understanding of these diseases and ensure that patients have timely access to life-saving and life-enhancing technologies.